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ABSTRACT

This study examines the importance of public review of federally funded scientific research by looking at several case studies. It shows that independent, nongovernmental review of federal scientific research has had a major positive effect on knowledge in many areas. The study focuses on: the Environmental Protection Agency and airborne asbestos; the panic over endocrine disrupters; the National Cancer Institute and the herbicide 2,4-D; the National Institutes of Health and the Dalkon Shield birth control device; and the Federal Drug Administration and the diet drug fen-phen. In many of those cases, third party review served to correct or prevent costly regulatory mistakes. In some cases, however, independent review of federally funded science occurred too late to prevent significant economic and consumer harm. The report considers the political, regulatory, and theoretical issues surrounding the Shelby Amendment, which requires federal agencies to ensure that all data produced under a grant be made available to the public through procedures established under the Freedom of Information Act. It concludes that the amendment, if fully complied with by federal agencies, will improve the quality of federal scientific research, and accordingly, the quality of federal regulation. (SM)

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THE CASE FOR PUBLIC ACCESS TO FEDERALLY FUNDED RESEARCH DATA

Policy Analysis, No. 366

Michael Gough and Steven Milloy

CATO Institute
February 2, 2000

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Routing

The Case for Public Access to Federally Funded Research Data

by Michael Gough and Steven Milloy

Executive Summary

Advocates of laws, regulations, and policies often use scientific data and analyses to advance their claims. In the normal course of science, controversies about data and analyses are resolved by independent researchers who attempt to replicate the data and redo the analyses. To facilitate independent review, the scientist who produces the data and analyses is generally expected to disclose his data and his methods to potential reviewers.

During the past three years, access to scientific data collected by federal grantees has become a major political issue. For instance, controversial scientific evidence was used to justify onerous regulation of particulate matter (a prominent air pollutant) and urban smog, but when Congress requested the controversial data, the grantees refused. In October 1998, Congress passed, and the president signed, Public Law 105-277, known as the Shelby Amendment. The law requires, through the provisions of the Freedom of Information Act, grantees to make data that result in a published report or that are cited in a federal rule or regulation available to members of the public on request.

Although the Shelby Amendment has drawn criticism from many policy activists and scientists, public review of data and methodology is crucial for both good science and good public policy. Scientific data collected by federal agencies have often been subjected to independent review and found to be in error. Scientific research undertaken by nongovernment scientists and financed with public money should similarly be available for review by public watchdogs to ensure that any new laws and regulations based on the research are merited. If the research is soundly grounded, then independent review will underscore the merits of those laws and regulations. If not, then independent review will help society avoid costly policy mistakes.

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Science flourishes in an atmosphere of free exchange of information.

The Nature of Science

The late Sir Karl Popper delved deeply into questions about the nature of science and how it works. He concluded that the scientific process, for all its accouterments of math, instrumentation, and specialized knowledge, can be divided into two parts. The first part is the formulation of an idea, hypothesis, or theory (the terms may be used interchangeably for present purposes) about how some part of the physical universe works. The second part is the design and execution of an experiment or test to discover whether the idea, hypothesis, or theory is corroborated or falsified. If it is corroborated, then the idea or hypothesis may be incorporated into scientists' knowledge of the universe, and it can be used in the construction of other ideas and hypotheses.[1] The distinguishing mark of science, according to Popper, is the formation of testable hypotheses.

The physicist Paul Davies underscored the importance of hypothesis testing:

> A powerful theory is one that is highly vulnerable to falsification, and so it can be tested in many detailed and specific ways. If the theory passes those tests, our confidence in the theory is reinforced. A theory that is too vague or general, or makes predictions concerning only circumstances beyond our ability to test, is of little value.[2]

In the process of testing hypotheses, scientists produce data, usually measurements or counts. To obtain recognition for their hypotheses and data, scientists must publish their findings, or "show their work," so that other scientists can examine and criticize those findings.

Scientists, like everyone else, can make mistakes. As Marcia Angell, a physician and executive editor of the *New England Journal of Medicine* and author of *Science on Trial: The Clash of Medical Evidence and the Law in the Breast Implant Case*,[3] said, "Many reports are trivial, many more are just plain wrong, and a lot of what we're told is inconsistent."[4] The accepted way to sort through reports of different value is through the process of critical review and attempted replication.

There's nothing shameful about a mistake, but scientists seek to avoid incorporating mistakes into accepted science. Additional ideas and hypotheses that are based on mistakes are almost certain to be wrong, and the time and effort expended on developing and testing those ideas and hypotheses are lost. It is far better to review, analyze, and attempt to replicate a new finding before accepting it.

Scientists have developed myriad methods for review. Scientists are expected to talk about their results and insights with their peers, and scientists who don't soon pass into obscurity, along with their work.

The primary method of dissemination and review of scientific results is through the publication of papers in scientific journals. Although journals have varying standards for review of papers submitted for publication, those with the most rigorous review processes tend to be the most prestigious.

Nevertheless, no matter how complete any published information is, a scientist interested in replicating or examining another scientist's work may have to call or write for additional details. There's no law against scientists' refusing to cooperate with requests for additional information; however, scientists who block the flow of information risk their reputations and undermine the credibility of their work.

Science flourishes in an atmosphere of free exchange of information.[5] Of course, some scientists—by their choice of employment—cut themselves off from completely open science. Scientists who work for defense companies, for example, can share information only on a need-to-know basis, and industry scientists may not participate openly in scientific exchanges because of concerns about patents, trade secrets, and other intellectual property.

Government-Funded Science

Scientific work that is used to support regulations, as is scientific work that is performed for industry, is done for a client. The industrial client may be more interested in using the science to foster the development of a product than in examining the soundness of the science, and the government client more interested in justifying a regulation. Unlike a business firm, which can face a disaster if it prematurely rushes a product to market, state regulators pass on to the public the losses entailed by poor regulation. Thus, because regulatory agencies are rarely penalized for erroneous science, they are less motivated to ensure that the science they use is valid. This leaves the process of checking the science, if it is to be done at all, to the public.

A provision in Public Law 105-277, known popularly as the Shelby Amendment and enacted by Congress in October 1998, guarantees, through the Freedom of Information Act, public access to grantee-collected data that are used in support of rules or regulations. The history of public review of federally collected data and analyses reveals the importance of such review in correcting errors made by government officials.

Data Used to Formulate Public Policy

Government data used to set regulations and to issue warnings and announcements about various products are of two types: (1) laboratory data and (2) epidemiologic data. In general, it's possible to conduct additional experiments and to attempt replication of laboratory studies.

It is impossible, however, to replicate epidemiologic studies, which provide information about unique populations of people, subject to unique conditions, over particular time periods, but the data from such studies can be reviewed and reanalyzed by independent scientists. The only way to determine the validity of those studies is through careful analysis of the techniques that were used to produce the data and through careful review of the analytic methodology adopted by the study's authors. Often it's not enough to have access to the published results of an epidemiologic study, because the underlying data sets can be too large to be incorporated into normal-length scientific articles. Similar problems with large data sets are common in economics and policy studies, and journals in those disciplines often require the authors of the papers to tell readers where the entire data sets are available.

This study examines the importance of public review of federally funded scientific research by examining a number of case studies. In the next six sections, we show that independent, nongovernmental review of federal scientific research has had a major positive effect on our knowledge about airborne asbestos, endocrine disrupters, the herbicide 2,4-D, the Dalkon Shield birth control device, and the diet drug fen-phen. In many of those cases, third-party review served to correct or prevent costly regulatory mistakes. In some cases, however, independent review of federally funded science occurred too late to prevent significant economic and consumer harm.

In the final section, we consider political, regulatory, and theoretical issues surrounding the Shelby Amendment. In sum, we conclude that the amendment, if fully complied with by federal agencies, will improve the quality of federal scientific research and, accordingly, the quality of federal regulation.

The EPA and Airborne Asbestos

In the last quarter century, "asbestos" has become synonymous with cancer, premature death, long-running lawsuits brought by former asbestos workers against the companies that mined and supplied asbestos, and billions of dollars in settlements for disease and death. That perception of asbestos is far different from the one that prevailed during World War II, when asbestos was used in great amounts in the construction of both warships and merchant ships, which were subject to airplane and submarine attacks. Asbestos saved the

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lives of many sailors. The building boom after World War II found more uses for asbestos—fireproofing, insulation for heating and cooling systems, soundproofing—and it was used in buildings of all sizes.

Before 1940 the asbestos industry was aware of the cancer-causing properties of asbestos. In the United States, the industry succeeded in keeping that information from the general public and health authorities.[6] (German health officials, however, instituted measures to reduce asbestos exposures in workplaces before and during World War II.)[7]

In 1955 Sir Richard Doll published a paper that clearly showed that exposure to asbestos greatly increased the risk of lung cancer and other deadly diseases.[8] After 1955, exposure to asbestos in U.S. workplaces was reduced. (There is an extensive and significant literature about the importance of interactions between smoking and asbestos exposure in causing lung cancer, but there is no doubt that exposure to asbestos in the workplace was a health risk.)

The realization that asbestos-containing materials (ACM) were present in many schools led parents in 1978 in some school districts in New Jersey to demand the removal of those materials. The issue came to the attention of the Environmental Protection Agency when the governor of New Jersey petitioned the agency to issue regulations for the control of asbestos in public buildings. Shortly thereafter, the Environmental Defense Fund petitioned EPA to issue regulations on control of asbestos in schools.

Between 1978 and 1990, EPA issued a series of rules and guidance documents about the management of exposure to asbestos in schools. The rules and guidance documents, all of which suggested that exposure to ACM was always a risk, caused many schools to rip out ACM, at costs from $7.5 billion to $16 billion.[9]

In 1990 EPA reversed course. It issued a guidance document that called for leaving ACM alone—"managing asbestos in place." That document provided for protection from asbestos without the huge costs called for in the previous documents. EPA has never explained the reason for its reversal, but, from the record, it is clear that entities that bore the costs of asbestos removal—former manufacturers of ACM and their insurers—had the capacity to generate their own measures of exposure and to attack EPA's previous misguided guidance documents.

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Asbestos Measurements

In 1982 EPA published measurements—incorrect as it turned out—of airborne asbestos. EPA contractors had collected samples of airborne asbestos in Houston schoolrooms and, using unconventional and invalidated methods, reported levels of airborne asbestos that approached levels found in workplaces where asbestos was mined or milled; used in the fabrication of asbestos-containing products; or installed as insulation or fireproofing in ships, buildings, and some appliances.[10] Former manufacturers of ACM used standard methods for collecting and measuring airborne asbestos and found much lower levels. Moreover, measurements of airborne asbestos in buildings around the world revealed low levels of asbestos that were often no different from levels in outdoor air or in buildings with no ACM.[11] (Asbestos is present in many minerals, such as "cats-eye" semiprecious stones and "rocks" of various kinds; in addition, natural processes release small amounts of asbestos into the air.)

Faced with measurements that did not support its own, EPA investigated the method that had been used in the Houston schools. EPA decided that the method was imprecise and unreliable and discarded it.[12] Had EPA listened to outside experts on measuring asbestos levels in the workplace, the agency would never have used the method that led to the mistaken measurements in Houston.

In the late 1980s, Congress ordered EPA to measure asbestos levels inside and outside public buildings. When it did so, using standard measurement techniques, EPA found there was essentially no difference between the two environments.[13]

EPA did not conclude, however, that low measured levels of exposure meant that the risks were low. EPA continued to argue that all ACM were a time bomb that would go off unexpectedly and shower building occupants with deadly concentrations of asbestos. The agency also argued that EPA-certified inspectors could somehow predict future releases on the basis of visual inspections.

By 1990, standard measurements revealed convincingly that the reports of EPA-certified inspectors about the danger posed by ACM bore no correlation with asbestos concentrations determined by measurements: the asbestos in ACM stayed put. The exception to that statement occurred when ACM were ripped out. Then exposure levels soared. The best management solution for ACM was to leave them alone until the building came down.[14]

Also in 1990, *Science*, one of the most respected scientific journals in the world, published a paper that showed that the risks from asbestos in buildings is very low.[15] For whatever reasons—maybe because of the prestige of *Science* or maybe because the readers of *Science* had read enough about the actual measurements of asbestos that they were ready to believe the article—the *Science* paper had a major impact and was widely reported in the newspapers and cited in Congress.

EPA Changes Its Mind

In late 1990, EPA issued another in its series of guidance documents about asbestos in buildings.[16] The document contained the following conclusions: health risk is related to the levels of airborne asbestos; those levels are low in buildings with ACM; the health risk "appears to be very low"; the removal of ACM is often not the best course of action and can increase exposures and risks; and building owners should keep an eye on ACM and repair or replace them when damaged. Finally, EPA required removal of ACM only when buildings are being renovated or demolished.[17] Thus, after a decade of arguing otherwise, EPA came around to the position taken by many occupational health experts from the beginning of the debates about asbestos in buildings.

In this case, it was the availability of measurement methods and opportunities for other parties to make independent measurements that discredited EPA's earlier rulings. Access to the agency's data was not necessary because methods for replicating those data were available and used.

Benefits and Costs

If there are any health benefits that resulted from the furor over asbestos in schools, those benefits are so small as to be undetectable.[18] And they may well be zero.

School systems and the taxpayers or the tuition payers that support the schools paid a very high price (between $7.5 billion and $16 billion) for ripping out ACM.[19] Former ACM manufacturers and their insurers paid large proportions of that money to school districts that successfully sued for recovery of their costs, and some former ACM manufacturers were plunged into bankruptcy.

No one was a winner except, maybe, owners of ACM inspection and removal companies. Even with the collapse of the asbestos-in-buildings scare, asbestos removal goes on. Banks often refuse loans for the purchase of buildings with ACM unless the seller or buyer agrees to remove the material. One estimate projects that, by 2020, an additional $50 billion will have been spent on asbestos removal.[20]

With the publication of its 1990 guidance document, EPA tacitly admitted its mistakes. However, EPA did not bear the costs of its misguided policies. School districts, ACM manufacturers and their insurers, and taxpayers, none of which benefited from EPA's policies, paid the price.

The Panic over Endocrine Disrupters

Theo Colborn, a scientist employed by the World Wildlife Fund, was convinced that industrial activity around the Great Lakes and chemical contamination of the lakes

In this case, it was the availability of measurement methods and opportunities for other parties to make independent measurements that discredited EPA's earlier rulings.

were the cause of a cancer epidemic. In her own words, it was a "great setback"[21] when she found no evidence of an epidemic. Of course, it was no setback for the people living around the lakes, only for her credibility as an expert on the effects of trace amounts of chemicals on human and animal health.

Colborn then turned to the literature on reports of deformed wildlife in the Great Lakes area. Such deformities have been reported for centuries, but Colborn theorized that industrial chemicals were to blame.

To explain the many different purported effects of the chemicals she observed, Colborn and others suggested that trace amounts of chemicals were affecting the functioning of endocrine hormones such as estrogen and testosterone. Those hormones play major roles in the development and functioning of many organ systems, and the hypothesis that chemical disruption of those hormones might produce a panoply of adverse effects wasn't without some merit. However, there was no evidence to support the hypothesis. The only experimental or clinical evidence for hormonal effects came from the study of exposure to powerful drugs that affect the endocrine system in human beings or livestock. However, those exposures weren't to run-of-the-mill "chemicals." They were exposures to drugs selected because they cause those effects. Moreover, the exposures weren't to low or trace levels of the drugs but to doses sufficient to cause observed clinical effects.

Colborn's coauthored book, *Our Stolen Future*,[22] which appeared in March 1996, was greeted with reservations by science writers in the major newspapers. Her explanation that trace amounts of chemicals were the cause of almost every adverse health effect ever described—from deformities to cancer to infertility to attention deficit disorder, from wildlife population explosions to wildlife population collapses—was generally thought too glib. And how, if she was correct, had legions of toxicologists and epidemiologists missed the pivotal role played by endocrine-disrupting chemicals in the wide-ranging investigations of the toxic effects of chemicals?

Five months after the publication of the Tulane results, scientists at a national meeting reported that they could not replicate those results.

The Tulane Study

The endocrine disrupter theory needed evidence to support it, and that evidence appeared in June 1996, when five scientists associated with John A. McLachlan at Tulane University published a paper in *Science*,[23] which has a reputation for rigorous prepublication review of papers. Those scientists reported that tiny amounts of pesticides, present at concentrations that are now permitted under EPA regulations, could interact and bind very strongly with hormone receptors—a first step toward affecting hormone-modulated biological systems. The researchers reported, for instance, that two pesticides present at concentrations at which neither had much effect independently were up to 1,600 times as potent in combination.

On the basis of their results, McLachlan and his coauthors suggested that regulations controlling pesticides needed to be tightened up. *Science*, which makes little or no effort to publicize most of the hundreds of papers it publishes each year, pulled out the stops with the McLachlan paper. It ran a news article about the experiment, complete with a picture of the Tulane researchers. It invited a scientist from the National Institutes of Health to write an article clarifying how the difficult-to-explain results might have come about. Those efforts paid off. The Tulane results were reported in major newspapers and on the TV evening news.

The Tulane results surprised many scientists. How could they have had no inkling of the synergistic effects of pesticides? After all, pesticides have been subject to thousands of tests. It turned out that those scientists hadn't missed the synergistic effects.

Five months after the publication of the Tulane results, scientists at a national meeting reported that they could not replicate the results of the Tulane study. In January 1997, scientists from universities, the federal government, and industry published a letter in *Science* that detailed their failures to replicate the Tulane results.[24] A month later, another group of scientists published a report of its attempts to replicate the Tulane results. In

Nature, those scientists dismissed the Tulane findings and their implications: "Our results do not support the assertion that synergism between estrogens is likely to present a major human or wildlife health concern."[25]

Confronted with the repudiation of their results and conclusions, the Tulane scientists first reacted by sticking to their guns. They suggested that minor differences between conditions and procedures in their laboratory and the other laboratories explained the discrepancies.[26] But 13 months after they published their alarming report, the Tulane scientists threw in the towel. In a letter in *Science*, McLachlan said:

> I write to formally withdraw the report "Synergistic activation of estrogen receptor with combinations of environmental chemicals."
>
> We have conducted experiments duplicating the conditions of our earlier work, but have not been able to replicate our initial results.
>
> Also . . . others have been unable to reproduce the results. . . . Meanwhile, people in many walks of life have, on their own, put great weight on this report as the basis of much discussion, thought, and even public policy.[27]

The last quoted sentence is disingenuous. In fact, in the original paper, McLachlan and his coauthors had suggested that their results would have public policy implications.

Tulane University investigated whether any fraud had been involved in the McLachlan paper. The university committee cleared McLachlan, but it concluded that Steven Arnold, the first author of the paper, "provided insufficient data to support the major conclusions of the *Science* paper"[28] and that "independent review of Arnold's data does not support the major conclusions."[29]

Science worked. Even though the reviewers for *Science* had not caught the faulty science before the paper was published, the requirement that scientists describe their experiments in enough detail that others can try to replicate them led to discovery of the mistake.

The Legislative Legacy of the Endocrine Disrupter Scare

Before he published his paper, McLachlan leaked the findings to EPA, and rumors about the paper's results were promoted by EPA staff in discussions with congressional staff. Those rumors were instrumental in the passage of the Food Quality Protection Act of 1996[30] and the Safe Drinking Water Act of 1996. Colborn's book and the Tulane results were especially instrumental in Congress's directing EPA to require new tests of commercial chemicals for endocrine disruption.[31]

The added testing may have a cost well beyond the economic one: it may cause disease and death. Bruce Ames, the recipient of the 1999 National Science Medal, has written extensively about the importance of eating fresh fruits and vegetables in preventing cancer.[32] One consequence of regulation of pesticides is that fruits and vegetables become more expensive and less available. Although the increases in price will not stop middle-class shoppers from buying fresh produce, low-income shoppers, whose diets are already far from optimal, may buy fewer fresh fruits and vegetables. If that is the case, their cancer risks will increase. Perversely, laws and regulations that are designed to protect consumers from the hypothetical risks that may accompany pesticide use can actually increase health risks.

When one considers all the adverse economic, and possibly adverse health, effects that stem from the Tulane study, the reaction of one government scientist to the study's unmasking is remarkable. Earl Gray, a scientist from an EPA laboratory, remarked, "I'm just glad it's starting to clear up for John McLachlan."[33] McLachlan's reputation is an issue, but he could have avoided tarnishing it by closer supervision of the work in his laboratory. Long after McLachlan's reputation starts "to clear up" for him, the country will still face billions of dollars in costs of chemical testing. Gray acknowledges that there is

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no justification for the testing that was added because of the Tulane study. "As for the hypothesis that hormonelike chemicals are dramatically more potent in combination, 'it's kind of fallen by the wayside since the paper was retracted,'" says Gray.[34]

At the beginning of the endocrine disrupter controversy, Congress commissioned the National Research Council to evaluate the evidence. The National Research Council's August 1999 report, issued long after Congress had passed the Food Quality Protection Act and the Safe Drinking Water Act, declared that the endocrine disrupter hypothesis was "rife with uncertainty" and that it was without clinical or experimental support.[35]

Gregg Easterbrook, commenting in the *New Republic* on the collapse of the endocrine disrupter scare, blistered Theo Colborn for the looseness of her reasoning.[36] As the evidence for her theory collapsed, Colborn declared that evidence isn't important: "Just because we don't have the evidence doesn't mean there are no effects."[37]

The National Cancer Institute and the Herbicide 2,4-D

In 1986 the National Cancer Institute published a study of Kansas farm workers that concluded that exposure to the herbicide 2,4-D increased cancer rates.[38] The finding was widely reported; homeowners who used 2,4-D on their lawns were frightened, and neighbors of those users were alarmed as well.

Manufacturers of 2,4-D found a significant flaw in NCI's study design when they were allowed access to it. The NCI scientists had asked farmers a question about 2,4-D use, and then asked only those who had reported 2,4-D use additional questions about herbicide use. When the NCI scientists stated the results of those questions, they reported information about "herbicide" use as "2,4-D" use. The NCI scientists admitted their error and published a corrected table,[39] but they have never explained how the error came about and how a question about herbicide was turned into a conclusion about 2,4-D.

Moreover, NCI depended on flimsy data. The only statistically significant increase in cancer was reported among workers exposed to herbicide (initially misreported as "2,4-D" exposure) on more than 21 days per year. How reasonable is it to assume that any individual can remember whether he used an herbicide for 1–2 days, 3–5 days, 6–10 days, 11–20 days, or more than 21 days per year over the past 15 or more years? According to the NCI analysis, the increased cancer risk from using herbicides for 1–2 days was greater than the risk from use for 3–5 and 6–10 days. The reported risk at 11–20 days was slightly greater than the risk at 1–2 days, and the risk at more than 21 days was highest of all. But only 11 workers (5 with cancer and 6 without) reported exposures of greater than 21 days, and the entire NCI analysis is based on the recall about herbicide exposure of 37 workers with cancer (or their next of kin). To draw any conclusion from those data appears to be a reach.

Follow-Up Studies Come Up Empty

Alarmed by the Kansas findings, a team of NCI scientists that included several authors of the Kansas study decided to investigate cancer incidence among farmers exposed to 2,4-D in Nebraska.[40] In the Nebraska study, published in 1990, the NCI scientists did ask about 2,4-D use, but they found no statistically significant cancer increase, even in workers who reported use of 2,4-D on more than 21 days per year.

The NCI reexamined its study of male farm workers and cancer incidence in Iowa and Minnesota. In that study, farmers were interviewed about chemical exposures between 1981 and 1984 but were not asked specifically about exposure to 2,4-D. NCI interviewers subsequently telephoned the Iowa and Minnesota participants in 1987–88 to inquire about 2,4-D use—four to seven years after the initial interviews.[41] For cases in which the participants had

died, the NCI scientists had to interview next of kin or neighbors to obtain proxy information about exposures. Although NCI steadfastly considers first-hand information gathered from workers and proxy information gathered from next of kin equally valid, comparison of directly reported and proxy data showed that proxy data were more likely to report exposures to widely used substances, such as 2,4-D, and less likely to report exposures to less widely used substances.[42] That's no surprise. People who work with chemicals are more likely to know the identity of the lesser-known substances than are people who do not.

Mixing direct data and proxy data appears to increase the chance that the data will show an association between 2,4-D and cancer. Even with the mixing of data, however, no excess of cancer incidence was associated with 2,4-D in the Iowa-Minnesota study.

Although collecting and analyzing the 2,4-D data gathered from the telephone survey delayed the publication of the NCI study by two years, there was no mention of the study when it appeared.[43] The NCI scientists also did not report the telephone survey data during their testimony to a special EPA committee that was considering regulation of 2,4-D.[44] To the considerable embarrassment of the NCI scientists who had ignored the data, industry scientists, who had obtained the data through FOIA requests, reported the data to the EPA committee.[45]

The NCI authors of the Iowa-Minnesota study explained that they had decided not to publish the results of the telephone survey because of weaknesses in the study.[46] Surely the weaknesses would have been evident during the planning and development of the telephone survey, but the NCI scientists plunged ahead, deciding against publication after the results were in.

The Dog Study

In 1991 the NCI was finally able to publish a report that seemed to substantiate the Kansas findings of an association between 2,4-D exposure and cancer. This time, the NCI claimed to have found an association between cancer in dogs and the dog owners' use of 2,4-D.[47] Like the NCI studies of farmers, the dog study attracted a lot of attention, and editorials drew attention to the similarities between the cancers reported in the farmers and in the dogs.

Industry officials had some doubts about the methods of analysis used by the authors of the dog study, and the officials requested the underlying data from the NCI. That organization stonewalled release of the data for more than 18 months. Although the dog owners' names had already been removed from the data, the NCI said that it was concerned that "industry" would use information about the breeds of the dogs and ZIP code locations to track down and harass the dog owners.

When the NCI finally released the data, scientists at Michigan State University reanalyzed the data. Their reanalysis revealed that the NCI-supported scientists had not clearly separated 2,4-D exposures from other chemical exposures. When exposures were adequately documented, the association between 2,4-D and cancer in dogs disappeared.[48]

The Lessons of 2,4-D

The 2,4-D saga shows the importance of citizens' having access to data so that they can check on the work of government scientists. In the 2,4-D studies, much of the research was done by NCI scientists—who are government employees—and that research was subject to FOIA requests. The errors that were revealed only after the data had been made available to other parties indicate quite clearly that mistakes can be made.

Manufacturers of 2,4-D have been harmed by the NCI reports. Every report of risk attracts attention and, probably, reduces sales, and every report of risk causes unwarranted worry on the part of users and consumers. However, reports that refute the cancer risk go largely unnoticed. "Bad news sells."

The NCI scientists have benefited from their work. Their institute is in the midst of what is expected to be 20-year, $100 million study of farmers' health. The failure to find

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any risk from 2,4-D after well over a decade's study has been translated into justification for looking for other risks or renewing the search for risks from 2,4-D, despite the fact that cancer rates among farmers are lower than among the general population.

Unfortunately, the flawed NCI studies of 2,4-D continue to have repercussions. The small number of scientists whose reputations depend on their reports of associations between 2,4-D exposure and cancer risk continue to refer to the NCI studies as support for their own results and conclusions. For instance, Lennart Hardell, associate professor of oncology at the Orebro Medical Center in Sweden, whose early reports showing significant increase in incidence of cancer from a few days' exposure to 2,4-D have never been replicated, and cannot be repeated, even by him,[49] cites without reservation the NCI studies as evidence for a 2,4-D association with cancer.[50]

The National Institutes of Health and the Dalkon Shield

The Dalkon Shield was an intrauterine birth control device (IUD) that was marketed by A. H. Robins Company beginning in 1971. In 1974 the U.S. Food and Drug Administration asked the company to remove the Dalkon Shield from the market because of reports of health problems. Later that year, the FDA said A. H. Robins could resume sales if a registry of users was kept. The company declined to keep a registry.

In 1976 the National Institutes of Health commenced the Women's Health Study to investigate the possible association between IUDs and pelvic infections. The study was published in 1981 and reported that IUDs, in general, increased the risk of pelvic infections by 60 percent.[51] The study was cited in litigation that eventually forced A. H. Robins into bankruptcy proceedings.

In 1991 researchers reexamined the original data from the Women's Health Study. They found that the authors of the original study had eliminated from the study, without any scientific basis, 52 percent of the women who had reported such infections and 25 percent of the women who had had no such infections. Moreover, the researchers who reexamined the data suggested that adverse publicity about IUDs at the time of the Women's Health Study could have affected patients' recall about their medical history and care and that doctors may have been more inclined to diagnose pelvic infections in women who used the Dalkon Shield. Summing up their reexamination, the authors of a 1991 report in the *Journal of Clinical Epidemiology* said the study that had linked the Dalkon Shield to pelvic infections "showed almost a complete disregard for epidemiological principles in its design, conduct, analysis and interpretation of results."[52]

However, the reanalysis was two years too late. In 1989, A. H. Robins was purchased by American Home Products, Inc., in what was then termed a "steal deal."[53] The Dalkon Shield was never reintroduced to the market.

The FDA and Fen-Phen

In August 1999, a Texas jury awarded $23 million to a former user of the diet drug fen-phen. The verdict went against American Home Products, Inc., which made fenfluramine, or the "fen" portion of fen-phen. The verdict cost American Home Products' stockholders $8 billion in share value in one afternoon and cast a pall over the future value of the stock.

Unscrupulous personal injury lawyers operating in an unbridled tort system deserve much of the blame for that verdict; however, a great deal of fault lies, as it did with similar verdicts in cases of silicone breast implants, with the Food and Drug Administration.

The controversy over fen-phen began in July 1997, when the *New England Journal of Medicine* rushed to publish a Mayo Clinic report detailing how 24 fen-phen users had experienced heart-valve damage.[54] The report

The failure to find any risk from 2,4-D after well over a decade's study has been translated into justification for looking for other risks or renewing the search for risks from 2,4-D.

was hardly an exhaustive scientific study. Only five of the claimed cases of heart-valve damage had actually been verified by surgical examination. The heart-valve damage reported in the remaining cases had been assumed from echocardiograms, which may not be sufficiently reliable. The study did not compare rates of heart-valve problems in fen-phen users with rates in nonusers. The actual number of cases of heart-valve damage was very small considering that millions of people had used or were using fen-phen at the time of the study.[53]

The FDA then sent in 1997 letters to physicians requesting information about heart-valve disease among fen-phen users. A month later, the FDA had collected 92 reports of disease among 291 patients tested. Within days—and despite the availability of less drastic options—the FDA called for a halt in fen-phen use and persuaded American Home Products to "voluntarily" pull fenfluramine and another diet drug, Redux, from the market.

There was no scientific evidence against fen-phen, such as a controlled comparison of heart-valve damage incidence among users and nonusers of the drug. If there had been real and significant problems with fen-phen, one would think they would have shown up much earlier and in many more individuals, since the drug had been used for years by millions of people. The FDA's hasty action opened the litigation floodgates, just as the agency's 1992 moratorium on silicone breast implants had done.[56] As of November 1999, only a few months after the decision of the Texas jury, more than 5,000 lawsuits had been filed across the nation by former users of fen-phen.

Three years after the FDA's action, though, it remains unclear whether fen-phen causes any harm. The American Heart Association says it's too soon to tell whether fen-phen caused significant damage to anyone and whether the effects wore off when use of fen-phen stopped. Furthermore, in the Texas case, the plaintiff's own cardiologist testified that her heart problems predated her use of fen-phen.

Could this series of events have been prevented? Perhaps. After the FDA browbeat American Home Products into withdrawing fenfluramine from the market, the agency refused to provide to the company the original data gathered in response to its letters to physicians, rendering American Home Products virtually defenseless.

The Shelby Amendment

Although members of the public had access to agency-collected data, until passage of the Shelby Amendment, they did not have access to data collected by agency grantees. The amendment came about because of Congress's and others' inability to obtain the data that underlay EPA's then-proposed stringent new air quality regulations, announced by EPA administrator Carol Browner in November 1996, for fine particulate matter (PM) and ozone.

The proposed regulations would be very expensive. EPA estimated that "partial attainment" of the required PM standard would cost $6.3 billion per year and that partial attainment of the ozone standard would cost $2.5 billion per year.[57] Pointing out that "partial attainment" has no legal or analytical basis, independent researchers estimated that the costs of full attainment would be between $69 billion and $144 billion per year for the PM standard and about $2.8 billion for the ozone standard.[58] EPA justified the regulations by claiming they would prevent 15,000 premature deaths per year. Given that the estimation of the health benefits of the regulations relied largely on a single controversial study, known as the "Pope study,"[59] that had never been verified or replicated, some scientists questioned whether the proposed rules, when implemented, would produce the health benefits claimed by EPA.[60]

Questions Surrounding the Pope Data

It is particularly remarkable that no one except the original researchers has ever seen the data that underlie EPA's air quality regulations. EPA, without ever having verified the

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data from the Pope study,[61] nevertheless heaped billions of dollars in regulatory costs on American industry, cities, and consumers.

The data on health, behavior, and exposure used in the Pope study were collected by the American Cancer Society through a telephone survey of 1 million people. The survey was conducted by 77,000 volunteers who, using a questionnaire prepared by the ACS, interviewed neighbors, family, and friends about their lifestyles and their health practices.

None of the information collected by the volunteers was validated or verified by an independent party. The interviewers were not well trained, and there was little quality control. How dependable are the data? Imagine asking a friend, neighbor, or relative about her smoking and drinking habits. How reliable will the answer be?

In the study, Pope and his coauthors combined the health-related information from the ACS survey with air pollution data. That study became the basis for EPA's November 1996 air quality regulations.

When industrial organizations and Congress asked to see the data used in the Pope study, EPA and the investigators denied the requests. Mary Nichols, then-head of the EPA's Office of Air and Radiation, put it this way: "We do not believe . . . there is a useful purpose for EPA to obtain the underlying data [since the studies were published in peer-reviewed journals]. . . . Securing more detail about this information is not necessary as part of EPA's public health standard-setting process."[62] In July 1997, EPA promulgated the new air quality regulations.

Pope eventually agreed to release the data to a committee of the Health Effects Institute, a group funded jointly by EPA and the automobile manufacturing industry. HEI is supposed to report its analysis of the data in 2000—three years after the regulations went into effect. But the agreement between the authors and HEI forbids members of the HEI committee to release the data to anyone else. The parties most affected by EPA's regulations—state and local governments, manufacturers, transportation companies, and the general public—are not allowed to see the data.

Congressional Action

Members of Congress who requested to see the data were irked by EPA's refusal to provide access to those data and were buffeted by complaints about the new regulations from organizations as diverse as the National Conference of Black Mayors and the American Farm Bureau. In 1997 members of Congress introduced legislation requiring the federal government to make data from federally funded research available to the public. That measure was defeated.

Less than a year later, in early 1998, Congress passed legislation that would have required the Office of Management and Budget to study the implications of public access to data from federally funded research. For unrelated reasons, President Clinton vetoed that legislation.

In October 1998, Sen. Richard Shelby (R-Ala.) introduced language to the appropriations bill that provided funding for OMB. The language, which remained in the legislation that was passed by Congress and signed by the president, required OMB to revise its rules

> to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through procedures established under the Freedom of Information Act.[63]

Ironically, the specific data that were requested by Congress are, according to EPA, not subject to the provisions of the amendment. The authors of this paper, under the auspices of the Citizens for the Integrity of Science, submitted an FOIA request to EPA for the Pope study data.[64] EPA refused, stating: "We are not providing the health survey data you seek, because these data are not in the Agency's possession. . . . Since the records were not produced under an EPA award, the Public Law cited as authority for your request is also not applicable."[65] EPA's interpretation

is probably correct, because OMB's Circular A-110 (discussed below), which incorporated the Shelby Amendment into rules for federal grantees, says that "the Federal Government has the right to obtain, reproduce, publish, or otherwise use the data first produced under an award [from the federal government]."[66] The health data used in the Pope study were first collected using ACS, not federal, funds.

OMB's Circular A-110

On February 4, 1999, OMB proposed OMB Circular A-110, a revision to federal grant policy to implement the Shelby Amendment. OMB received more than 9,000 comments on the proposal, with 55 percent of the respondents supporting the proposed revisions. In August 1999, OMB issued a clarification to the revision, which garnered 3,000 comments.

OMB's final revision to Circular A-110, issued on October 8, 1999,[67] provides that a private citizen can make an FOIA request to a federal agency that has supported research for any data produced with federal funding and that has resulted in a published report. A report is "published" when it appears in a scientific or technical journal or when "a Federal agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law."[68]

This language excludes research results that are not published in the scientific or technical literature or translated into policy and rules. The result is that data from much federally supported research are still not accessible. In particular, data that are used in formulating government risk assessments or in promulgating "guidelines" cannot be obtained under the provisions of Circular A-110.

The wording of the circular excluded from FOIA requests "preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues." In addition, it provides protection for trade secrets and similar materials and for personal medical information "which would constitute a clearly unwarranted invasion of personal privacy." The party making the request can be charged for all the expenses necessary to obtain the data.

In the summer of 1999, a number of legislative efforts were made to repeal or to delay implementation of the Shelby Amendment. None was successful.

Arguments against Data Access

During the debate over access to the Pope study data, EPA insisted there was nothing to be gained from the public's having access to the data. The agency insisted that the data are accurate and that the analysis is well done.

That may be true; however, since EPA officials deny ever having examined the data,[69] we wonder how they could possibly know. Science is rooted in skepticism, including skepticism about one's own work. The physicist Richard Feynman, one of the century's great scientists, cautioned about fallibility. In science, he wrote, "the first principle is that you must not fool yourself and you're the easiest person to fool." It's a stretch to think that that first principle applied to Feynman but not to the authors of the Pope study.

Before OMB issued its regulations implementing the Shelby Amendment, some scientific organizations, including the National Academy of Sciences,[70] objected to implementation of the new law. The NAS argued that the law, by making scientists comply with data requests, would open up to public scrutiny notebooks from every federally supported laboratory and hobble scientific research. OMB's language for Circular A-110 put some of those concerns aside by limiting access to data that are used in published reports or cited for the development of rules and regulations.

George Thurston, an EPA contractor whose study results have also been used by the agency to justify new regulations, said, "If past history is any indication, vested interests will misuse [the Shelby Amendment] to discredit valid research results they don't like and to harass the researchers doing the work."[71] As the history of opposition to the PM regulations demonstrates, "vested inter-

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Protecting the privacy of individuals who participate in studies is often difficult, but it's not impossible.

ests" include many government organizations and industrial concerns. The largest class of "vested interests" consists of taxpayers who paid for the research and who will eventually bear the costs of the regulations. Surely, "vested" or not, those organizations and individuals should be able to see the data on which regulations are based.

Thurston and other EPA-supported scientists supposedly put their motives above those of industry-employed scientists, who are pictured as being willing to do anything for money or other incentives. Angell sees many reports about health matters, which is the type of "scientific" information that interests most people. She is quite clear in stating that government-supported scientists are subject to pressures and enticements, just as other scientists may be. In answer to a question about government reports, Angell said, "We're naive if we think government isn't subject to political considerations."[12]

Proprietary Data and Privacy Concerns

At least two issues that arise with data access—proprietary interest in data and protection of the privacy of study participants—deserve serious thought and action.

Scientists can work for years to develop databases, and then they can spend years "mining" those data and producing publications. Nevertheless, when the data are used to impose regulations on organizations and individuals, those organizations and individuals have proprietary interests in the data. The scientists' proprietary rights to their data are certainly a consideration, and provisions are made in FOIA to protect them. However, those rights should not override the right of the public to have access to those data.

Protecting the privacy of individuals who participate in studies is often difficult, but it's not impossible. For example, the Agent Orange study by the U.S. Air Force, one of the most politically sensitive epidemiologic studies done by the government, shows that the privacy of individuals can be preserved. The study, which began in 1982 and will end with a reexamination in 2002, investigated the health of the 1,200 Air Force personnel who sprayed 90 percent of the Agent Orange used during the Vietnam War. At five-year intervals, each of the 1,200 people who participated in spraying Agent Orange and a comparable number of Air Force personnel who flew similar aircraft in Southeast Asia during the Vietnam War but did not spray Agent Orange undergo a thorough physical and psychological examination.

The Air Force's response to requests for data from that study illuminates how such requests can and should be handled. In 1990 Air Force scientists were contacted by veterans' groups about releasing the data from the study. After a discussion with the Department of Health and Human Services committee that oversaw the Air Force study, the decision was made that the data would be made available to anyone who requested them.

The Air Force and the advisory committee were very concerned with protecting the privacy of the study participants. Accordingly, the National Center for Health Statistics "scrubbed" the data to remove personal identifiers.

Releasing personal data about health is not a trivial matter, and the Agent Orange study by the Air Force demonstrates that confidentiality of study participants can be preserved. Furthermore, FOIA rules and Circular A-110 provide for the protection of the identity of study participants.

Conclusion

The Shelby Amendment makes government regulators who depend on scientific data to justify their actions more responsible to the public. The amendment may, as Senator Shelby acknowledged, introduce some unexpected problems as OMB implements the law; however, as he also stated, those problems can be dealt with as they arise.

Two potential problems are already apparent: (1) the new data access rules do not apply to grants issued prior to the date on which the OMB regulations were issued and

(2) the rules apply only to actions that have the force and effect of law. The result of the first problem is that the Pope study data, for example, can be used ad infinitum by EPA without ever being made available to the public. We recommend that Congress fix that loophole by directing OMB to implement the data access law so that data from all significant scientific studies funded and relied on by a federal agency, regardless of the date of the grant, can be made available on request. With regard to the second problem, the legislative history of the data access law included federal policy as well as rules. However, the current OMB implementation exempts federal policy from the law. The effect is that agency policies, most notably for health and environmental risk assessments, which can have significant societal impact, are not covered by the data access rule. We recommend that Congress direct OMB to revise its implementation of the law to apply to any significant federal regulatory action, including policy.

The concern that flawed scientific research—immune from independent review—may be used to justify misguided and costly regulations is well grounded in fact. Without independent review of scientific data and methodological practices, policy mistakes are inevitable.

Although legislative efforts to stall or block the Shelby Amendment failed in the summer of 1999, they may be resurrected in the future. One argument that is certain to be used against the amendment is that it's "a backdoor way"[13] to interfere with regulatory programs. Imbedded in such arguments is the idea that the government cannot be questioned. The government and its scientists appear to be as prone to mistakes as anyone else. Requiring the government "to show its work" opens up the regulatory process. Moreover, it ensures that federal regulations are based on sound science and reduces doubts about the need for federal intervention. Whether one supports or opposes regulatory action, we should all acknowledge that independent review of scientific data and methodology can serve only to strengthen the scientific foundations of public policy.

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